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**International Travel for Living Donor Kidney Donation: A Proposal for Focused Screening of Vulnerable Groups**

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**Abstract:**

As the gap between organ donors and patients on the recipient waiting list grows, residents of the US who are in need of kidney transplantation occasionally contract with living donors from outside the US. Those donors then travel to the US to undergo living donor kidney donation at US transplant centers. This practice is not limited to the US and occurs with some regularity around the world. However, there is very little written about this practice from the perspective of the US transplant system, and there is little in the way of guidance (either legal or ethical) to assist centers that accommodate it in distinguishing between ethically permissible travel for transplant and what could potentially be human trafficking for organ removal. This paper will present an ethical analysis of travel for organ donation with particular attention to lessons that can be drawn from living donor donation in other countries. This inquiry is particularly germane because OPTN has promulgated guidelines with respect to obligations owed to living donors, but those guidelines appear to assume that the donor is a US resident. The critical question then, is whether and/or to what extent those guidelines are applicable to the instant scenario in which the living donor is a non-resident. In addition, this paper addresses several critical ethical concerns implicated by the often vulnerable populations from which donors are drawn. Finally, this paper proposes that focused inquiry by transplant centers is necessary when donors are non-residents.

## **I. Introduction**

Residents of the United States, who require kidney transplantation occasionally contract with living donors from outside the U.S. These individuals then travel to this country to undergo living donor kidney donation at U.S. transplant centers. These scenarios, while rare, give rise to particular ethical challenges, most notably in developing effective screening measures to evaluate potential donors for Human Trafficking for Organ Donation (HTOR), and secondarily, in ensuring adequate post-donation follow up care.

Data compiled by OPTN indicate that between March 31, 2015 (the date on which OPTN began tracking donor country of origin) and December 31, 2017, United States transplant centers reported 307 kidney transplants using non-U.S. resident non-U.S. citizen living donors (hereafter non-resident LDs), who traveled to the U.S. for the sole purposes of serving as a kidney donor.<sup>1</sup> In general, this population tends to be biologically related to the recipient.<sup>1</sup> Those who are not are generally acquainted in some way – a spouse, a friend, or an in-law, for example.<sup>1</sup>

However, a small number of non-resident LDs appear to have no pre-existing relationship with the recipient whatsoever. Specifically, in 2016, the first full year for which data are available, there were 12 living kidney donors who were not acquainted with the recipient prior to donation.<sup>1</sup> In 2017, nine LDs fell into this category.<sup>1</sup> There were a total of 24 between March 31, 2015 and January 31, 2018, of which 15 were donors in a paired donation scenario that was their sole reason for their being in this country.<sup>1</sup> Unacquainted LDs are particularly problematic from an ethical perspective as the altruistic motivations for such donations are difficult to verify. Moreover, this group is “the most frequent source of organs for transplant tourists” and the individuals are “often victims of exploitation and coercion.”<sup>2, 3</sup>

It is important to emphasize the limited scope of this issue so as to avoid the insinuation that there is a rampant, unchecked practice of non-resident non-citizens organ donors coming to the U.S. Between January of 2016 and December of 2017, there were a total of 208 individuals in this narrow category.<sup>1</sup> During that same period of time, there were more than 11,000 living kidney donations, making the practice an exceedingly small occurrence (less than 2% of LDs) within the overall transplant system. However, the very fact that there are a limited number of these donors raises a second concern: verification of adequate post-donation care in compliance with OPTN Policy 18.5.A.<sup>4,5</sup> As discussed in more detail below, transplant centers could conceivably fail to obtain post-donation data on this entire category of donors, while still complying with OPTN policies regarding thresholds for data reporting.

This article proposes that focused screening should be required to evaluate whether a non-resident LD is an ethically appropriate candidate for living kidney donation. In furtherance of this objective, Appendix A (SDC, <http://links.lww.com/TP/B776>) provides a set of screening questions that centers can use to evaluate these donors for their risk of HTOR. Of note, this screening tool has not yet been validated and future research will be necessary to determine whether this, or similar screening tools are effective at identifying and excluding inappropriate non-resident LDs. Nevertheless, targeted questioning is important for those who travel exclusively for purposes of organ donation because the very fact of their traveling for purposes of transplantation makes evaluation of their motivation for donation particularly difficult. Appendix A (SDC, <http://links.lww.com/TP/B776>) takes the existing “Social History” screening recommendations set forth in Policy 14 (eg, Occupation, Employment status, Insurance status, Social support) and draws on the established literature, international recommendations, and practices for non-resident LDs to encourage the kind of focused scrutiny this group requires.

## **II. The risk of HTOR: international perspectives and U.S. applications.**

Organ trafficking is “the unjust practice of using a vulnerable segment of a country or population (defined by social or economic status, ethnicity, gender or age) as a source of organs.”<sup>6</sup> Pursuant to the UN Protocol to Prevent, Suppress, and Punish Trafficking, it can include, “the recruitment, transport, transfer, harboring or receipt of persons, by means of the threat or use of force or other forms of coercion [...] for the purpose of exploitation by the removal of organs.”<sup>6</sup> As noted by Yousaf and Purkayastha, identifying HTOR can be exceptionally difficult. While organ trafficking certainly includes the removal of organs from donors who have been subjected to coercion or abuse, “the boundary between consent or coercion may be less clear” when trafficking is involved than when it is not.<sup>7</sup> This is for a variety of reasons including that victims of trafficking are frequently also victims of “severe economic and social exploitation” making their motivation for donation unclear.<sup>7</sup> Additionally, given the number of individuals involved in the HTOR chain, it can be difficult to identify whether the donor is acquiescing to an abuser or other person in a position of power within that chain, or is motivated by a financial transaction.<sup>7</sup>

The National Organ Transplant Act of 1984 in the United States was drafted largely to prevent organ trading *within* the U.S.<sup>8,9</sup> and is, therefore, of limited utility in combatting transplant practices involving international travel. Likewise, current OPTN policies do not specifically address scenarios involving non-resident LDs. For example, Policy 17 pertaining to “International Organ Transplantation” includes guidance on the use of deceased donor organs from foreign sources, but does not include a corresponding section on living donor organs.<sup>10</sup>

OPTN Policy 14 sets forth guidelines for living donation including guidelines for the psychosocial evaluation of living donors.<sup>11</sup> These guidelines require, among other things, “an assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate.”<sup>11</sup> This policy also requires exclusion of donors where there is a “high suspicion of donor coercion” or a “high suspicion of illegal financial exchange between donor and recipient.”<sup>11</sup> In addition, Policy 14.4.A provides categories of evaluation and assessment of all living donors. Categories include evaluation of the donor’s social history and specifically include inquiry into donors’ “occupation, employment status, health insurance status, living arrangements, and social support.”<sup>11</sup> Although OPTN Policies provide helpful guidance, the specific evaluation process is set by the transplant centers, which themselves may not be attuned to the inquiries necessary when the donor is not a resident of the U.S.

In contrast, the international community has proposed a number of potential approaches to LDs who are not residents of the country in which they will donate. Notably, the 2017 “Resolution on the principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors,” promulgated by the Council of Europe, identifies this group as “particularly vulnerable” and needing “additional measures [...] to ensure their protection and care.”<sup>12</sup> This includes procedures to verify the relationship between the donor and the recipient and limiting LDs to those who have a pre-existing relationship (preferably first- or second-degree genetic relatives or spouses).<sup>12</sup>

This echoes the work done by those concerned with HTOR, internationally. Notably, Dominguez-Gil, et al have previously identified several “red flags” that should alert health professionals during the screening process to a high risk of HTOR. These include:

Memorized or mechanically recited stories; fearful demeanor in the potential donor; inability to produce official documentation verifying the relationship between donor and recipient; documents in the possession of a third party; absence of a common language between donor and recipient; previous refusal of donation in another center, or residence in a country where living donor transplantation is available.<sup>2</sup>

Others have advocated for international reporting systems that would encourage collaboration among countries and individual clinicians to address the lack of both jurisdiction and specific legislation that can frustrate attempts to penalize those engaging in HTOR.<sup>9, 7, 13</sup> An interesting perspective by Capron, et al suggests that collaboration between prosecutors and healthcare providers could also be an effective tool in combatting HTOR.<sup>14</sup> The focused screening set forth in Appendix A (SDC, <http://links.lww.com/TP/B776>) is informed by the commentary of the international community as tailored to the unique setting of the U.S. healthcare system.

#### A. Potential for Inappropriate Financial Exchanges

One concern in a non-resident LD scenario is that the forms that financial coercion could take are perhaps less easily identifiable. The Council of Europe has noted that the appropriate reimbursement to a LD should include the costs of travel, accommodations, loss of earnings, and various medical expenses.<sup>12</sup> This is consistent with NOTA which allows “expenses of travel, housing, and lost wages incurred by the donor.”<sup>4</sup>

In the context of a non-resident LD, though, these expenses are more difficult to categorize. Without Medicare and/or private insurance covering the cost of care,<sup>15</sup> one could imagine a potential kidney recipient incentivizing donation with excessive, but ostensibly legal “reimbursable medical expenses.” Additionally, a resident living unrelated donor is more likely

to be a spouse or life partner.<sup>16</sup> Therefore, while psychological coercion remains a potential risk, the risk of financial coercion is presumably lower.

Transplant centers also should be conscientious of individuals who may be using the money received from kidney donation to pay off debt accrued in countries with very little social and economic mobility. For perspective, a recent examination of LDs who were deemed to be part of HTOR in India revealed that 98% reported debt and a desire to “transcend poverty” as their reason for donating a kidney.<sup>17</sup> Similarly, 93% of victims of HTOR in Pakistan were motivated by the desire to repay a debt.<sup>13</sup> Research also suggests that victims of organ trafficking are consistently “poorly educated, unemployed, and uninsured individuals living under the poverty line” in countries where there is a “destitute underclass.”<sup>3, 6</sup> This concern is particularly germane as data collected by OPTN show a consistent number of LDs travel to the U.S. from developing nations.<sup>1</sup>

Ironically, available data also show that kidney donation rarely actually improves economic standing, and victims of HTOR generally report that their lives are worse after donation owing in large part to a lack of appropriate post-transplant medical care.<sup>6, 13, 17</sup> Thus, inquiry into the financial motivation and situation of the donor are important factors to consider with a non-resident LD.

#### B. Identification of vulnerability in non-resident LDs

Transplant centers should be attuned to the risk of HTOR in several specific demographics. These include women from countries in which women have limited social power and economic mobility.<sup>17</sup> For example, research indicates that husbands in India occasionally pressure their wives to sell a kidney.<sup>6</sup> In contrast, in Egypt, Iran, Pakistan, and the Philippines,



men are the more vulnerable demographic owing to the financial pressure that results from being the primary “breadwinners” for their family.<sup>6, 18</sup>

Similarly, scrutiny should be given to individuals who are religious, ethnic, or cultural minorities in their country of origin. In such cases, transplant centers should endeavor to ensure that the LD’s country of origin does not engage in the kind of systematic, economic disenfranchisement that occasionally motivates individuals to donate kidneys as a “last resort.” The U.S. State Department’s Bureau of Democracy, Human Rights & Labor publishes annual reports on the human rights conditions of individual countries through its webpage (<https://www.state.gov/j/drl/rls/hrrpt/>), making this information relatively easy to access.<sup>19</sup> Individuals can select a country they wish to better understand along with various potential human rights issues (e.g. “Freedom of Religion” or “Protection of Refugees”) and receive an instant report detailing the status of those issues in that particular country.<sup>19</sup> Such reports could assist in evaluating transplant pairs.

Transplant centers further should be cautious about accepting LDs who may be refugees. Advocates such as Dr. Debra Budiani-Saberi, the Director for the Coalition for Organ Failure Solutions, have previously highlighted the plight of Sudanese refugees in Egypt who have been victimized by trafficking in kidneys.<sup>20</sup> The coalition has reported that the exploitation of refugees likely includes individuals from Jordan, Eritrea, Ethiopia, Somalia, Iraq, and Syria.<sup>20</sup> While there is no indication that donors from any of these countries have entered the U.S. transplant system, the potential for exploitation of the world’s growing refugee populations requires focused, case-by-case screening of non-resident LDs, particularly in light of the potential for confusion regarding country of origin once refugees are granted passports from their country of asylum.

C. Entry into the U.S. may be coercive in itself.

Transplant centers should consider that some LDs may use donation to gain entrance to the U.S. with no intent to return to their home country. Several European countries that allow non-resident LDs have reported this as a concern there.<sup>21</sup> This concern should not be mistaken for a desire to keep foreigners out of the U.S., but rather acknowledges that providing potential pathways to residency in the U.S. may itself be a coercive factor for LDs. On this point, the Council of Europe's Resolution urges that clear procedures should be established for lawful entry into the country as well as exit post donation.<sup>12</sup> Unfortunately, the Resolution does not detail what such procedures might look like, though one could imagine they might include some accountability by the transplant center or recipient if donors consistently fail to return to their country of origin in accordance with their visa.

At the heart of each of these considerations is the recognition that individuals who travel from other countries to serve as LDs in the U.S. do so for a variety of reasons, some of which may place them at risk of being victims of HTOR.

### **III. Existing OPTN Policies Do Not Adequately Address Follow-up Care For Non-Resident Living Donors**

In February 2013, OPTN promulgated guidelines pertaining to data collection requirements and duties of care extending from transplant centers to LDs. The guidelines advance four primary objectives: 1. Conviction that follow-up is essential for donor safety and well-being; 2. Importance of building and maintaining a relationship with each donor; 3. Use of a systemic approach to follow-up, with ongoing quality assurance activities; 4. Use of strategies to minimize burdens to donors.<sup>3</sup> In furtherance of these goals, OPTN recommends significant QA and QI initiatives (including transplant center-based policies) that include extensive data collection and monitoring of living donors.<sup>5</sup>

Overall, these guidelines appear to assume the donor is a U.S. resident as they consistently reference desired coordination with the donor's primary care physician, face-to-face, long-term follow up care, and an assumption that follow-up care will be reimbursed through some combination of Medicare or private insurance of either the donor or the recipient.<sup>5</sup> OPTN policy 18.5 also favors two full years of follow up with LDs.<sup>4</sup> Further, OPTN's "Procedures to collect post donation follow up data from living donors" repeatedly emphasizes that "follow-up care is essential for donor safety and well-being,"<sup>5</sup> suggesting that transplant centers obtain the name of the donor's primary care physician prior to donation, and requests that the donor's PCP complete a pre-donation evaluation specifically to "ensure that donors have established a relationship with a PCP so that post-donation follow-up care is more likely."<sup>5</sup>

Post-operatively, OPTN instructs transplant centers to send a discharge summary to the donor's PCP and to attempt to "see the donor for face-to-face follow-up visits at the medical center or contact the donor and the donor's PCP if the PCP will be collecting the follow-up data."<sup>5</sup> OPTN goes on to provide a number of strategies for ensuring successful follow-up care including having multiple ways of contacting the donor (e.g. mail, email, cell phone), obtaining contact information for family members of the donor, and calling the donor from the clinician's cell phone to encourage donors to take the call.<sup>5</sup> OPTN Policy 18.5 states that this follow up period "will be a minimum of two years."<sup>4</sup>

Despite OPTN's emphasis on follow-up care for living donors, including striving for "100% ascertainment of LDF [living donor follow-up] data,"<sup>5</sup> Policy 18.5 only requires centers to successfully follow 80% of living kidney donors.<sup>4</sup> Reportable data include, among other things, post-donation donor status and one-year post-donation donor lab values.<sup>4, 5</sup> However, because the number of non-resident LDs is approximately 2% of all LDs, centers could fail to

follow up on all non-resident donors and remain in compliance with OPTN policies. Although such a practice might comply with OPTN transplant policies, it would violate the ethical principle of justice, which requires that allocation strategies not disproportionately burden or disadvantage specific individuals.

A. Transplant centers have an ethical obligation to all donors including non-resident donors.

Ideally, LDs come from countries in which they have access to regular medical care, as well as a primary care physician with whom the U.S. transplant center can coordinate follow-up care. This is likely the case for donors from, for example, Canada, who comprised a large proportion of non-resident living kidney donors.<sup>1</sup> However, a significant number of LDs, including those from Mexico, India, and other developing nations are less likely to have access to post-transplant care when they return home. For example, research done by Gutierrez, et al, in 2012, revealed that nearly half of “the Mexican population had no effective access to health services.”<sup>22</sup> Assuring opportunities for standard, post-donation follow up care is consistent with ethical principles of beneficence and non-maleficence. When such care cannot be reasonably assured, transplant centers may be returning LDs to countries in which access to follow-up care is unknown or may be known to be inadequate.

UNOS’s educational information for donors acknowledges the relative lack of data on long-term outcomes even for resident living donors.<sup>23</sup> Risks are thought to be generally low, but may include hypertension, reduced kidney function, hernia, organ failure, or possibly death.<sup>13</sup> UNOS also identifies the potential for psychological risks following donation including anxiety or depression.<sup>13</sup> These risks potentially may be greater in non-resident donors from the developing world owing to their lack of access to follow up care. Specifically, in the study of victims of HTOR from India referenced above, 89% of donors reported a deterioration in their

health since donation.<sup>17</sup> Additionally, 43% reported “a loss of dignity” tied to the stigma associated with serving as an organ donor.<sup>17</sup> One hundred percent of those individuals interviewed stated they regretted the commercial removal of their kidney.<sup>17</sup> While the experiences of individuals involved in HTOR may not translate exactly to non-resident donation in the U.S., these findings do suggest that a cautious approach should be taken.

#### **IV. Discussion and Recommendations**

Transplant centers that allow donation from non-resident LDs confront two primary obstacles: (1) screening for potential HTOR; and (2) ensuring the LD has access to appropriate post-transplant care. There are multiple opportunities built into the donor registration process during which focused screening of non-resident LDs can occur. Specifically, standard initial screening questionnaires require LDs to provide a permanent address. The use of a non-U.S. address should trigger targeted, tailored questioning of LDs throughout the entire donation journey. For example, in our own transplant center, all LDs are interviewed by a psychologist who assesses the psychosocial history of the donor, and the relationship between the LD and the intended recipient.<sup>24</sup> This is followed by a meeting with the Living Donor Advocate, who specifically screens to ensure the LD is acting voluntarily.<sup>24</sup> Thereafter, the LD meets with the transplant social worker who ensures the LD has adequate post-operative support.<sup>24</sup>

The set of questions provided in Appendix A (SDC, <http://links.lww.com/TP/B776>) - or similar ones modified to work with individual transplant centers - could be used during this evaluation process as an initial risk screening tool. While this screening does not provide a “score” or threshold for exclusion, it does highlight known risk factors for HTOR and encourages deeper engagement with the psychosocial picture of LDs who are not U.S. residents. Centers, already adept at identifying inappropriate donors who *are* U.S. residents, likewise

should exclude those LDs whose totality of circumstances indicate a high risk of coercion or a likelihood of lack of access to post-operative treatment. We further recommend that unacquainted LDs who cannot articulate an acceptable or altruistic purpose for participating in organ donation (e.g. they are part of a paired donation scenario in which they have a relationship with the recipient of the other pair) should be excluded.

Further, LDs who are unrelated to the recipient, who belong to ethnic or religious minorities in their country of origin, or who are impoverished in a country that lacks financial mobility—all factors which may suggest particular risk of HTOR—should be closely evaluated to confirm their motivation for donation is truly altruistic. Additionally, given the opaque nature of expenses for non-resident donors, centers should consider requesting copies of checks provided to the LD or establish monitored escrow accounts from which all funds paid to the non-resident LD must be drawn. This may aid in ensuring that reimbursement does not violate NOTA's prohibition on valuable consideration in exchange for transplantable organs.

As it relates to follow-up care, non-resident LDs also require additional consideration. There are a number of factors which may make non-resident LDs high risk for being lost to follow-up. As noted by Dominguez-Gill, non-resident LDs are more likely to present language barriers.<sup>2</sup> These language barriers extend beyond the LD, to the clinicians who would ostensibly be providing care to that individual after they return home. Additional obstacles may include cultural differences and difficulty accessing medical records from foreign healthcare systems. However, OPTN guidelines require that a LD be viewed as an individual, autonomous patient to whom ethical obligations extend. To that end, while OPTN's policies were not written with non-resident LDs in mind, many of them can and should be extended to non-resident LD transplants.

For example, OPTN has instructed transplant centers to assign living donors an independent donor advocate or coordinator who is a social worker or other clinician and is not involved in the care of the organ recipient.<sup>5</sup> This individual is responsible for answering health-related questions, coordinating follow up care, monitoring outcomes, and tracking data. They could also be responsible for ensuring a more complete informed consent process that specifically details the risks unique to non-resident donors such as difficulty coordinating post-transplant care with a U.S. transplant center.

Likewise, OPTN's recommended QA/QI initiatives include extensive data collection and monitoring of LDs. As it pertains to non-resident donors, transplant centers should track specific data on how frequently they lose contact with non-resident LDs and whether patterns emerge that LDs from specific countries are more difficult (or impossible) to track than others. Where data indicate that follow-up is consistently problematic with respect to specific countries, transplant centers should avoid accepting donors from those countries.

As noted above, OPTN guidelines assume two full years of extensive follow-up care for donors, including interfacing with the donor's primary care physician, or establishing a "donor clinic" at which the living donor can receive care.<sup>4,5</sup> For many non-resident donors, this will not pose an obstacle. Donors from countries with well-established healthcare infrastructure will, in all likelihood, have post-transplant care available to them at home, minimizing concerns that the donor is returning to an unknown future.

For other donors, it may be necessary to provide accommodations for extended stays in the U.S. to monitor post-transplant health in compliance with OPTN guidelines. Alternatively, to the extent LDs are returning to their home country relatively soon after surgery, transplant centers should ensure they have multiple ways to contact both the donor and his physician.

Ultimately, OPTN policy 18.5.A may need to be revised to require that transplant centers obtain follow-up data on at least 80% of non-resident LDs. This would eliminate the current loophole, which allows omission of post-transplant data from all non-resident LDs.

Finally, moving forward under an assumption that some donors may be at a higher risk of post-transplant organ failure than others, centers may want to explore providing priority status to donors who subsequently require organ transplantation as a result of having served as a donor.

## **V. Conclusion**

Organ transplantations involving non-citizen non-resident LDs pose unique ethical challenges. Extraordinary care should be taken to ensure that such donors are freely and altruistically motivated. This both protects the donor from potential exploitation, and insulates the center from allegations of HTOR. Additionally, where post-transplant care is known to be unavailable to the donor, it would not be ethically permissible, nor would the process be compliant with OPTN policies, to perform the organ transplantation and then return the donor to his or her country of origin. Rather, in accordance with the recommendations above, centers should consider allowing donors to remain in the U.S. for an extended period of time to ensure adequate post-transplant care. Adhering to additional screening measures such as those suggested above and set forth in the attached appendix (SDC, <http://links.lww.com/TP/B776>) will assist transplant centers in identifying those donors for whom additional protections, or even outright exclusion, is appropriate.



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